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10/071,877	02/08/2002	Robert C. Downs	36-001810US	9765

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EXAMINER

SINES, BRIAN J

ART UNIT	PAPER NUMBER
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1743

MAIL DATE	DELIVERY MODE
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09/06/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/071,877	Applicant(s) DOWNS ET AL.	
	Examiner Brian J. Sines	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9,11-23,30-43,45-58,113 and 114 is/are pending in the application.
- 4a) Of the above claim(s) 59-71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9,11-23,30-43,45-58,113 and 114 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 2/8/2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/14/2007 has been entered.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the robot that is capable of inserting two or more sample vessels into the sample receiving regions at substantially the same time, wherein the sample receiving regions comprise one or more non-vertical clusters, must be shown and labeled or the feature(s) canceled from the claim(s). In addition, the longitudinal axes of the non-vertical axes of the sample receiving regions must be shown and labeled. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the

Art Unit: 1743

drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 – 9, 11 – 23, 30 – 43, 45 – 58 and 113 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "member sample receiving regions" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 113 recites the limitation "member sample receiving regions" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1743

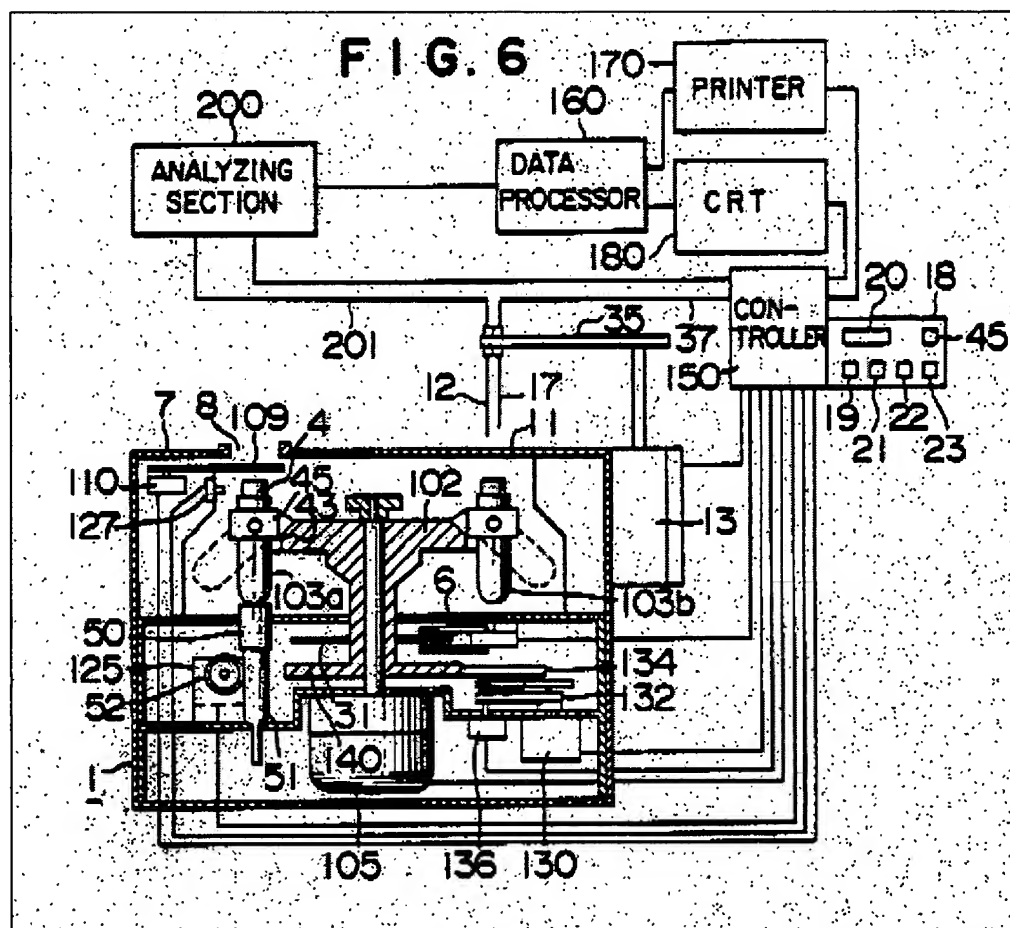
The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1 – 9, 11 – 21, 23, 30 – 38, 42, 43, 45 – 49, 53, 54 and 56 – 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshida et al. (U.S. Pat. No. 4,708,940) (“Yoshida”) in view of Jovanovich et al. (U.S. Pat. No. 6,423,536 B1) (“Jovanovich”), and further in view of Pang et al. (U.S. Pat. No. 6,060,022 A) (“Pang”).

Regarding claims 1, 9, 14, 16, 19, 20, 21, 32, 48 and 58, Yoshida teaches an apparatus comprising: centrifuge rotor (102) comprising a plurality of sample receiving regions (e.g., pot holder 103a) and sample vessels (sample pot 4); and a transport mechanism (e.g., driving device 13 & arm 35) configured to move a processing component(s) (e.g., sample take-out pipe or tube 12 & sensing electrode 17) proximal or within the plurality of sample receiving regions 103a (see col. 2, line 28 – col. 7, line 63; figure 6). As shown in figure 6, the sample receiving regions 103a can be arranged in a non-vertical position during operation. It should be noted that claim 1 does not positively recite that the sample receiving regions are arranged in a *fixed* or permanent non-vertical configuration.

Art Unit: 1743

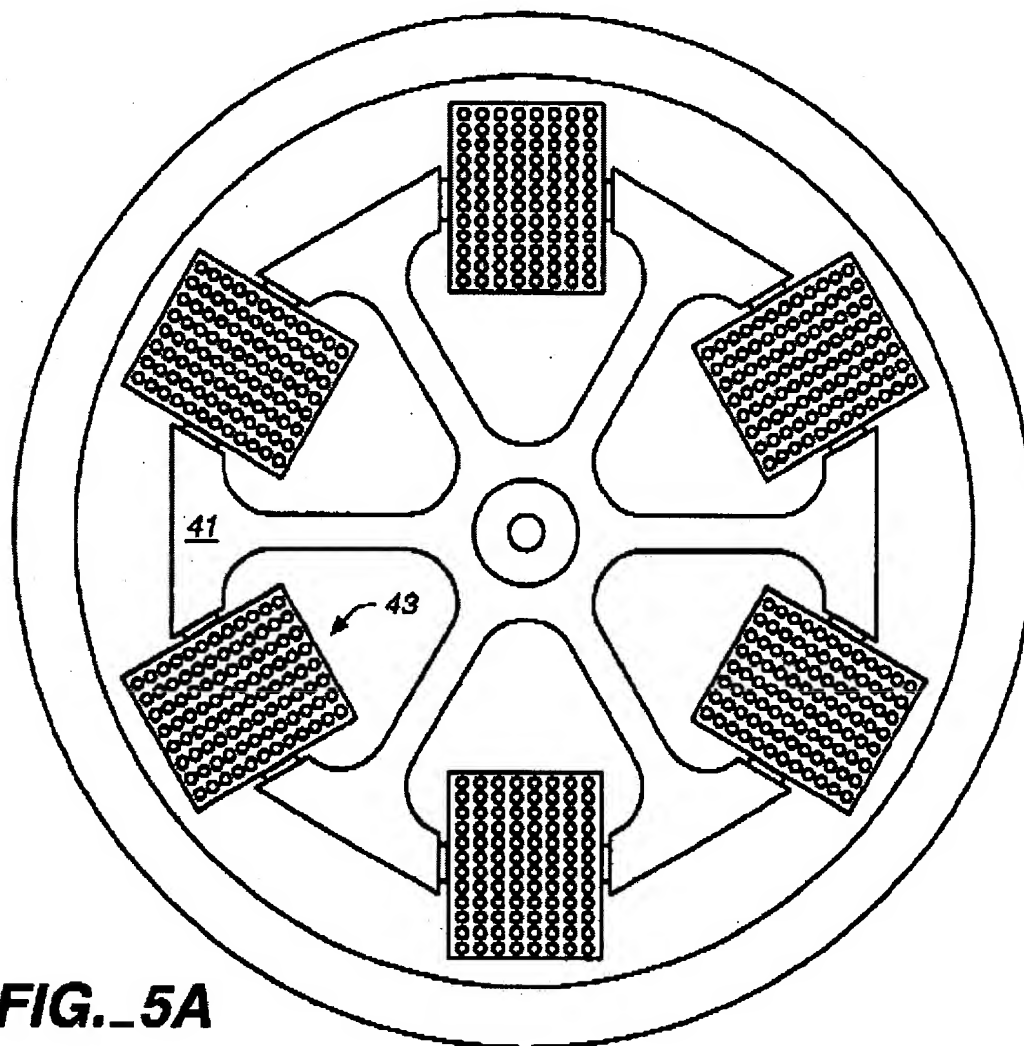


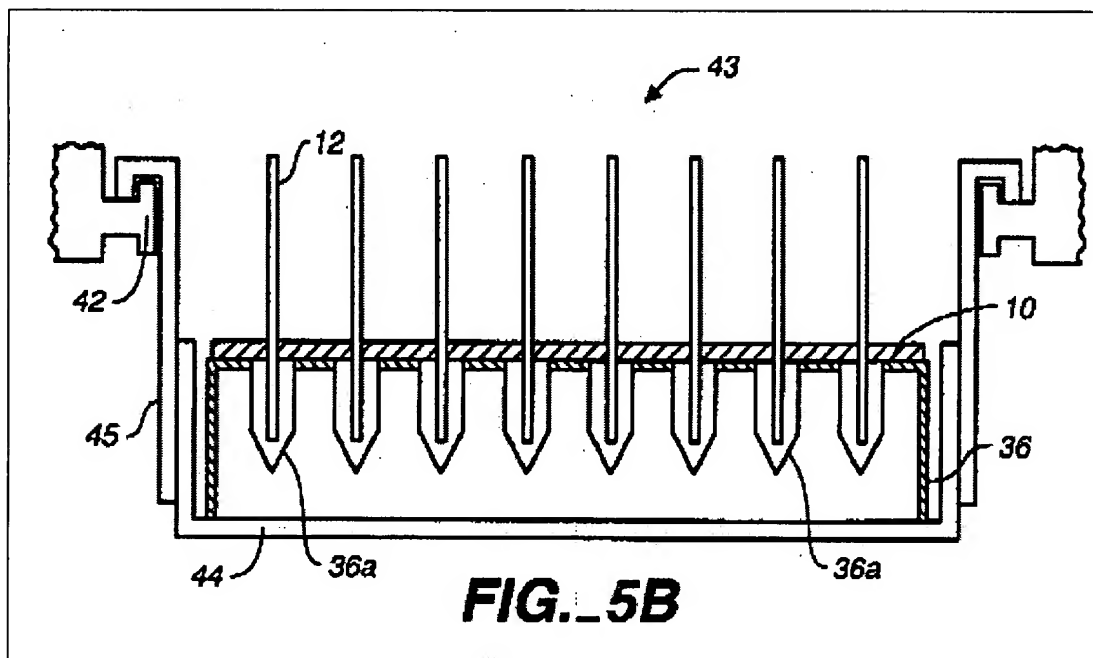
Yoshida does teach the use of a transport mechanism (e.g., driving device 13 & arm 35) configured to move two processing component(s) (e.g., sample take-out pipe 12 & sensing electrode 17) proximal or within one of the sample receiving regions 103a at a time (see col. 2, line 28 – col. 7, line 63; figure 6).

Yoshida does not specifically teach the incorporation of a transport mechanism that is configured to move one or more processing components proximal to or within each of two or more sample receiving regions comprising a plurality of sample-holding vessels at substantially the same time, wherein the sample processing components are configured to be inserted into the sample vessels when the sample vessels are present in the rotor.

Art Unit: 1743

Jovanovich does teach an automated centrifuge system comprising: a microplate bucket (43); centrifuge (42); and a transport mechanism (e.g., automated robot 102 comprising transfer head 104 containing capillary cassette 15) that is configured to move one or more processing components (capillary tubes 12) proximal to or within each of two or more sample vessels (wells 36a of multiwell plate 36) at substantially the same time, wherein the sample processing components are configured to be inserted into the sample vessels when the sample vessels are present in the rotor (41) (see figures 1, 5A and 5B; col. 9, line 56 – col. 11, line 17).





As shown by Jovanovich, a person of ordinary skill in the art would accordingly have had a reasonable expectation for success in using a robotic transport mechanism for moving one or more processing components, i.e., sample fluid transfer tubes, proximal to or within two or more sample vessels, e.g., wells of a multi-well plate, at the same time and when the sample vessels are present within the rotor. The Courts have held that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02). In addition, the Courts have held that the mere duplication of parts, without any new or unexpected results, is within the ambit of one of ordinary skill in the art. See *In re Harza*, 124 USPQ 378 (CCPA 1960) (see MPEP § 2144.04). Furthermore, the applicant is advised that the United States Supreme Court recently clarified that a claim can be proved obvious merely by showing that the combination of known elements was obvious to try. In this regard, the U.S. Supreme Court explained that, “[w]hen there is a design need or market pressure to solve a

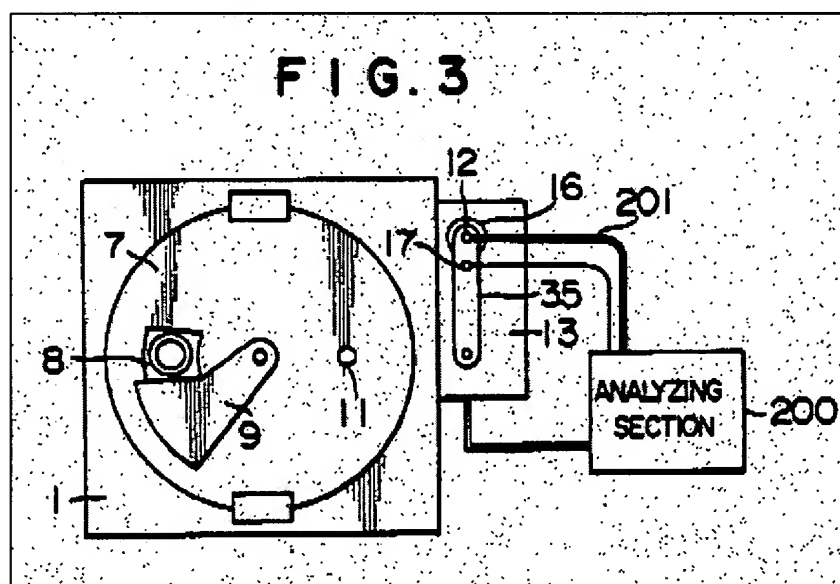
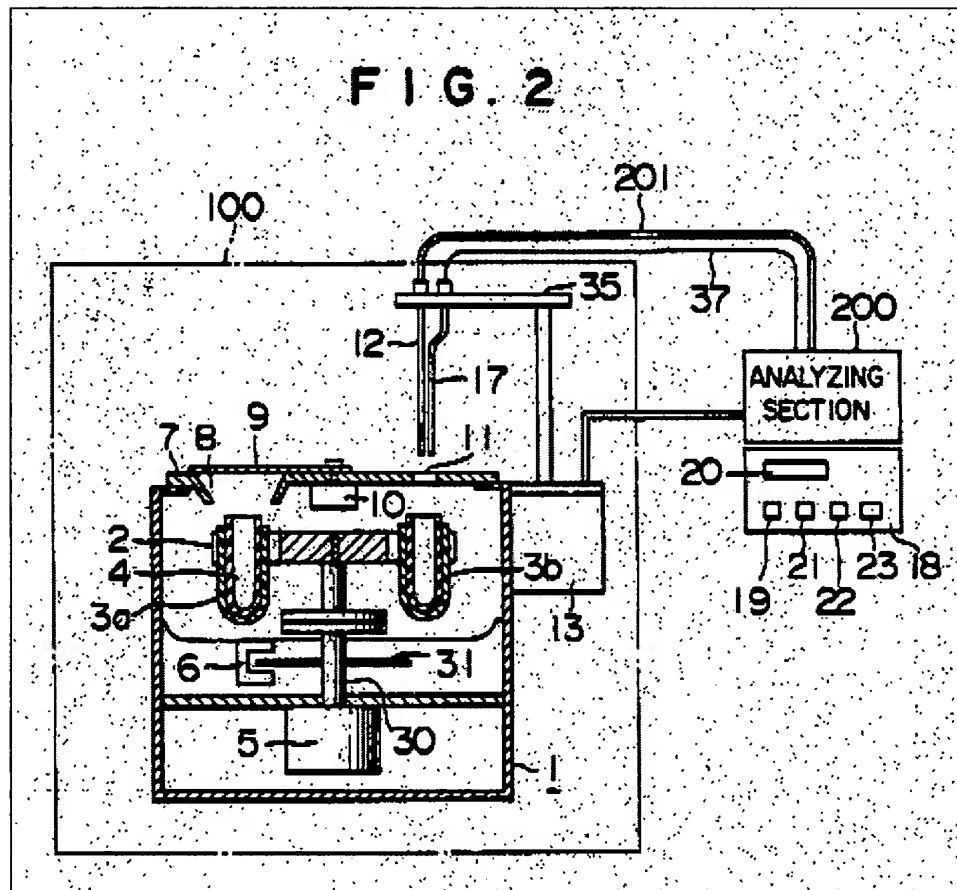
Art Unit: 1743

problem and there are a finite number of identified, predictable solutions, a person of ordinary skill in the art has a good reason to pursue the known options within his or her technical grasp.”

An obviousness determination is not the result of a rigid formula disassociated from the consideration of the facts of the case. Indeed, the common sense of those skilled in the art demonstrates why some combinations would have been obvious where others would not. (“The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.”). See *KSR Int’l v. Teleflex Inc.*, 127 Sup. Ct. 1727, 1742, 82 USPQ2d 1385, 1397 (2007). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate the transport mechanism as claimed with the disclosed centrifuge device to facilitate effective sample processing.

Regarding claims 2 and 3, Yoshida teaches the incorporation of an optical rotor position sensor (e.g., photocoupler 6) (see col. 3, lines 29 – 59).

Regarding claim 4, Yoshida teaches the incorporation of a centrifuge chamber (e.g, the container comprising centrifugal separator 1) and a rotor cover (lid 9) (see figures 2 & 3; col. 3, lines 29 – 59).



Art Unit: 1743

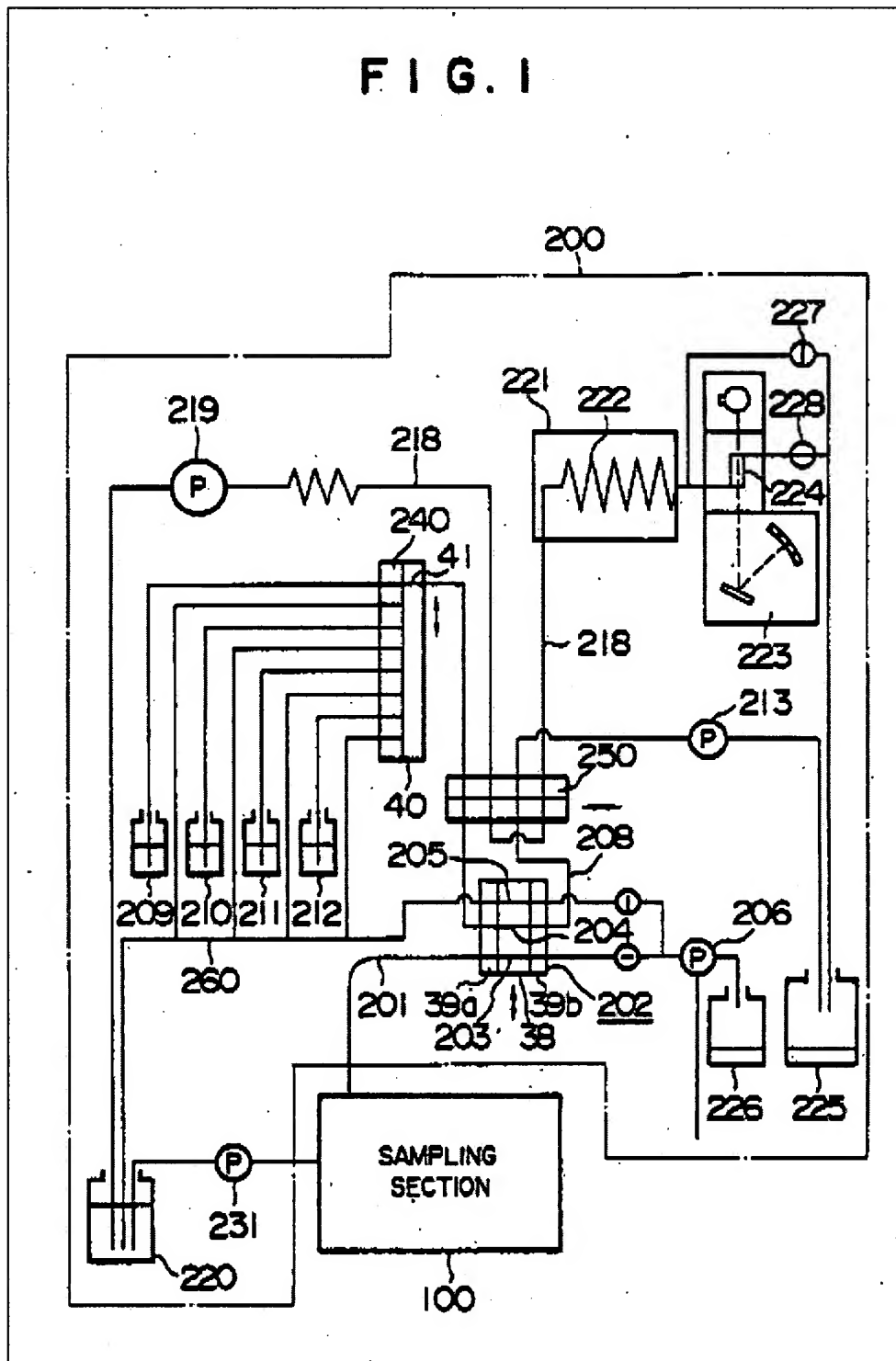
Regarding claims 5 and 35, Yoshida teaches the incorporation of a reference index (e.g., disk 31 & pot detector 127), which facilitates rotor positioning (see col. 3, lines 29 – 48; figures 2 & 6).

Regarding claims 6 – 8, Yoshida teaches the incorporation of a motor (driving device 5) (see col. 3, lines 29 – 48).

Regarding claims 30, 31, 33, 34, 36 – 38, 42 and 43, Yoshida teaches the incorporation of a controller (150) comprising a microcomputer for operating the disclosed apparatus (see col. 7, lines 9 – 16). Therefore, it would have been obvious to a person of ordinary skill in the art to provide appropriate software for monitoring and controlling the automated centrifuge system.

Regarding claims 49, 53 and 54, Yoshida teaches the incorporation of an analyzing section (200) comprising a specimen collector (e.g., flow cell 224), which collects a specimen for analysis (see col. 5, line 35 – col. 63; figure 1).

Regarding claim 55, it would have been obvious to a person of ordinary skill in the art to incorporate a fraction dispensing element, such as tubing positioned within a test tube, for the specimen collection. The use of tubing is well known in the art to facilitate sample fluid transfer (see MPEP § 2144.03).



Regarding claim 46, Yoshida teaches the incorporation of a rinsing or washing means (e.g., washing tube 16) (see col. 4, lines 5 – 17; figure 3).

Regarding claim 47, Yoshida teaches the incorporation of a rinsing or washing means (e.g., washing tube 16) (see col. 4, lines 5 – 17; figure 3). Yoshida does not indicate the incorporation of two bins, tubes or containers and a runoff ramp. The Courts have held that the mere duplication of parts, without any new or unexpected results, is within the ambit of one of ordinary skill in the art. See *In re Harza*, 124 USPQ 378 (CCPA 1960) (see MPEP § 2144.04). Therefore, it would have been obvious to incorporate two containers for rinsing. The use of ramps for directing fluid flow are well known in the art (see MPEP 2144.03). Therefore, it would have been obvious to incorporate a runoff ramp with the disclosed apparatus for facilitating runoff fluid flow.

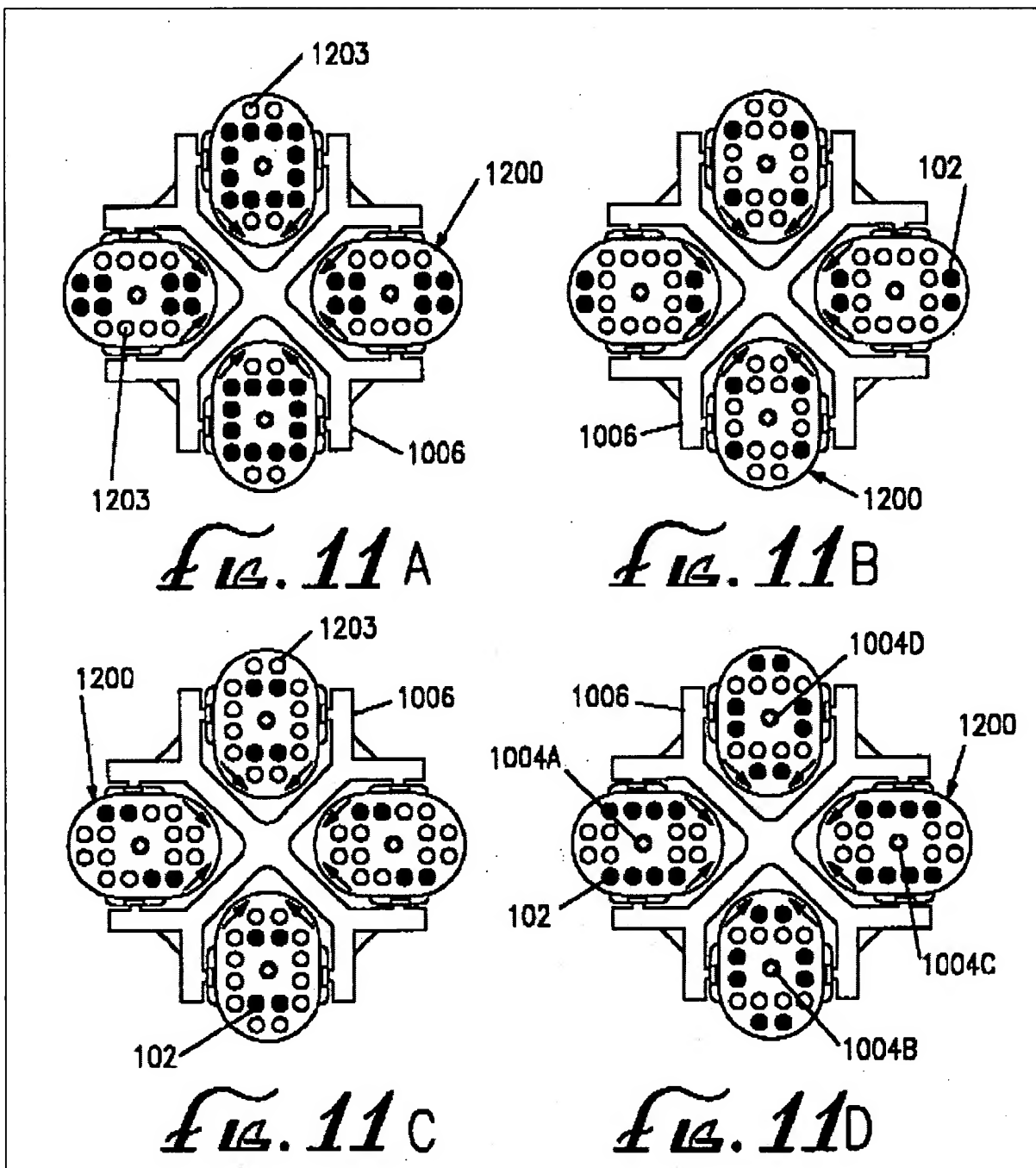
Regarding claim 56, the incorporation of second transport mechanism with the disclosed apparatus would have been obvious to a person of ordinary skill in the art. The Courts have held that the mere duplication of parts, without any new or unexpected results, is within the ambit of one of ordinary skill in the art. See *In re Harza*, 124 USPQ 378 (CCPA 1960) (see MPEP § 2144.04).

Regarding claim 57, Yoshida teaches an apparatus comprising: sample receiving regions (e.g., pot holder 103a) and sample vessels (sample pot 4); various sample processing components (e.g., sample take-out pipe 12 & sensing electrode 17); various hoses (e.g., sample transfer pipe 201), which inherently have tips or ends; various pumps (206, 213, 219 & 231); a fluid source (e.g., reagent reservoirs 209 – 212); a specimen collector (e.g., flow cell 224); various switches or valves (e.g., switching valves 240, 250, movable valve 40, slide valve 202); a waste dump (e.g., washing tube 16) (see col. 3, line 1 - col. 7, line 64; figures 1 – 3, 6 & 7). The Court has recognized that an artisan is presumed to have skill, rather than lack of skill. See *In re Sovish*,

Art Unit: 1743

226 USPQ 771 (Fed. Cir. 1985). It would have been obvious to a person of ordinary skill in the art to provide appropriate tubing or hose connections, pump connections, etc., between the various system components as claimed to facilitate effective device operation.

With respect to claims 1, 11 – 13, 15, 17, 18 and 23, neither Yoshida nor Jovanovich specifically teach the incorporation of a sample cluster configuration comprising a plurality of sample-holding vessels. As shown by Pang, the use of a clustered sample holding configuration in addition to a robotic mechanism with automated centrifuge systems is well known in the art (see, e.g., col. 20, line 59 – col. 21, line 3; figures 11A – 11D). Pang teaches that each cluster or bucket 1200 holds a plurality of containers 12 or test tubes 102 (see col. 11, lines 25 – 54). Hence, a person of ordinary skill in the art would accordingly have had a reasonable expectation for success of incorporating such a clustered configuration including a robotic transport mechanism with an automated centrifuge system (see MPEP § 2143.02). Furthermore, the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. See *KSR Int'l v. Teleflex Inc.*, 127 Sup. Ct. 1727, 1742, 82 USPQ2d 1385, 1397 (2007). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a clustered configuration with an automated centrifuge system.



Regarding claim 45, the incorporation of a second rotor as claimed would have been obvious to a person of ordinary skill in the art. The Courts have held that the mere duplication of parts, without any new or unexpected results, is within the ambit of one of ordinary skill in the art. See *In re Harza*, 124 USPQ 378 (CCPA 1960) (see MPEP § 2144.04).

2. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshida, Pang and Jovanovich, and further in view of Alam et al. (U.S Pat. No. 5,792,050 A) (“Alam”).

Regarding claim 22, the aforementioned cited prior art does not specifically teach the incorporation of a sonication apparatus. Although Yoshida does teach the incorporation of a fluid transfer tube (e.g., sample transfer pipe 201 & sample take-out pipe 12) (see col. 3, line 29 – col. 6, line 57; figures 2 & 3). Yoshida does teach that the disclosed apparatus is utilized in analyzing blood samples (see col. 1, lines 1 – 16). As evidenced by Alam, the use of sonication probes in assisting in the biochemical analysis of blood samples is well known in the art (see col. 6, lines 55 – 65). Thus, a person of ordinary skill in the art would accordingly have had a reasonable expectation for success of utilizing a sonication device in facilitating the analysis of blood samples. In addition, the Courts have held that the mere duplication of parts, without any new or unexpected results, is within the ambit of one of ordinary skill in the art. See *In re Harza*, 124 USPQ 378 (CCPA 1960) (see MPEP § 2144.04). Furthermore, the Courts have held that to provide a mechanical or automatic means to replace manual activity, which accomplishes the same result, is within the ambit of a person of ordinary skill in the art. See *In re Venner*, 120 USPQ 192 (CCPA 1958). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a plurality of sonication devices and fluid transfer tubes as claimed with the disclosed apparatus.

3. Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshida, Pang and Jovanovich, and further in view of Roginski et al. (U.S Pat. No. 4,927,545) (“Roginski”).

Art Unit: 1743

Regarding claim 41, the above cited prior art does not specifically teach the incorporation of a recognition means with the disclosed apparatus. Roginski teaches the incorporation of a recognition means (e.g., barcode reader 28, 78 & optical sensor 24) (see col. 1, line 29 - col. 8, line 36). Furthermore, the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. See *KSR Int'l v. Teleflex Inc.*, 127 Sup. Ct. 1727, 1742, 82 USPQ2d 1385, 1397 (2007). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a recognition means with the centrifuge system for facilitating effective sample processing.

4. Claims 39 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshida, Pang and Jovanovich, and further in view of Taylor (U.S Pat. No. 4,822,331) ("Taylor").

Regarding claims 39 and 40, the aforementioned cited prior art does not specifically teach the incorporation of operator safety members. As shown by Taylor, the incorporation of safety mechanisms with laboratory equipment comprising a centrifuge is well known in the art. Taylor does teach the incorporation of a safety member (e.g., motor 103, clutch 160, stop sleeve 171, relay 154, contact 151, run switch 59 & stop switch 185) with a centrifuge apparatus (see col. 8, line 3 – col. 11, line 20). Thus, as evidenced by Taylor, a person of ordinary skill in the art would accordingly have had a reasonable expectation for success in incorporating the use of a safety mechanism with the centrifuge system. Furthermore, the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. See *KSR Int'l v. Teleflex Inc.*, 127 Sup. Ct. 1727, 1742, 82 USPQ2d 1385, 1397 (2007).

Art Unit: 1743

Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate such a safety mechanism as claimed with the disclosed apparatus, in order to provide safe operation.

5. Claims 50 – 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshida, Pang and Jovanovich, and further in view of Feldman (U.S Pat. No. 5,445,958 A) (“Feldman”).

Regarding claims 50 – 52, the aforementioned cited prior art does teach the incorporation of a sample analyzing section (200) (see col. 5, lines 35 – 46). In addition, the above cited prior art does not specifically teach the incorporation of a sample purification apparatus comprising a nickel-chelate resin. Yoshida does teach that the disclosed apparatus is utilized in analyzing blood samples (see col. 1, lines 1 – 16). As evidenced by Feldman, the use of liquid column chromatography utilizing a nickel-chelate resin, such as a chelating sepharose resin comprising immobilized iminodiacetic acid groups, in the separation and analysis of blood plasma samples is well known in the art (see col. 4, line 29 – col. 8, line 55). In addition, the Courts have held that the selection of a known material, which is based upon its suitability for the intended use, is within the ambit of one of ordinary skill in the art. See *In re Leshin*, 125 USPQ 416 (CCPA 1960) (see MPEP § 2144.07). Furthermore, the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. See *KSR Int’l v. Teleflex Inc.*, 127 Sup. Ct. 1727, 1742, 82 USPQ2d 1385, 1397 (2007). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate such a separation component as claimed with the disclosed apparatus.

Art Unit: 1743

6. Claim 113 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshida in view of Roginski, and further in view of Pang.

Regarding claim 113, Yoshida teaches an apparatus comprising: centrifuge rotor (102) comprising a plurality of sample receiving regions (e.g., pot holder 103a) and sample vessels (sample pot 4); and a transport mechanism (e.g., driving device 13 & arm 35) configured to move a processing component(s) (e.g., sample take-out pipe 12 & sensing electrode 17) proximal or within the plurality of sample receiving regions, wherein the sample processing components are configured to be inserted into the sample vessels when the sample vessels are present within the rotor (see col. 2, line 28 – col. 7, line 63; figure 6). As shown in figure 6, the sample receiving regions 103a can be arranged in a non-vertical position during operation. It should be noted that claim 113 does not positively recite that the sample receiving regions are arranged in a *fixed* or permanent non-vertical configuration.

Yoshida does not specifically teach the incorporation of a robot for inserting a sample vessel into a sample receiving region. Roginski teaches an apparatus comprising a robotic arm (10) including a gripper (14) for transporting test tubes (18) to and from a centrifuge (20) for facilitating blood sample analysis (see col. 3, line 29 – col. 4, line 65; figure 1). As shown in figure 1, the centrifuge (20) comprises a single non-vertical fixed-angle cluster comprising receiving regions for test tubes. The Courts have held that things clearly shown in a reference patent drawing qualify as prior art features, even though they are unexplained by the specification. See *In re Marz*, 173 USPQ 25 (CCPA 1972). Furthermore, the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. See *KSR Int'l v. Teleflex Inc.*, 127 Sup. Ct. 1727, 1742, 82 USPQ2d

Art Unit: 1743

1385, 1397 (2007). Hence, a person of ordinary skill in the art would have recognized the suitability of incorporating a robotic arm with an automated centrifuge apparatus. As evidenced by Roginski, a person of ordinary skill in the art would accordingly have had a reasonable expectation of success of incorporating such a robotic arm mechanism with an automated analytical apparatus comprising a centrifuge. Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a robotic arm as claimed with the disclosed apparatus.

Yoshida does not specifically teach the incorporation of a sample cluster configuration comprising a plurality of sample-holding vessels. As shown by Pang, the use of a clustered sample holding configuration in addition to a robotic mechanism with automated centrifuge systems is well known in the art (see, e.g., col. 20, line 59 – col. 21, line 3; figures 11A – 11D). Pang teaches that each cluster or bucket 1200 holds a plurality of containers 12 or test tubes 102 (see col. 11, lines 25 – 54). Hence, a person of ordinary skill in the art would accordingly have had a reasonable expectation for success of incorporating such a clustered configuration including a robotic transport mechanism with an automated centrifuge system (see MPEP § 2143.02). Furthermore, the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. See *KSR Int'l v. Teleflex Inc.*, 127 Sup. Ct. 1727, 1742, 82 USPQ2d 1385, 1397 (2007). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a clustered configuration with an automated centrifuge system.

7. Claim 114 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshida in view of Jovanovich.

Art Unit: 1743

Regarding claim 114, Yoshida teaches an apparatus comprising: centrifuge rotor (102) comprising a plurality of sample receiving regions (e.g., pot holder 103a) and sample vessels (sample pot 4); and a transport mechanism (e.g., driving device 13 & arm 35) configured to move a processing component(s) (e.g., sample take-out pipe or tube 12 & sensing electrode 17) proximal or within the plurality of sample receiving regions, wherein the sample processing components are configured to be inserted into the sample vessels when the sample vessels are present within the rotor (see col. 2, line 28 – col. 7, line 63; figure 6). As shown in figure 6, the sample receiving regions 103a can be arranged in a non-vertical position during operation. It should be noted that claim 114 does not positively recite that the sample receiving regions are arranged in a *fixed* or permanent non-vertical configuration.

Yoshida does teach the use of a transport mechanism (e.g., driving device 13 & arm 35) configured to move two processing component(s) (e.g., sample take-out pipe 12 & sensing electrode 17) proximal or within one of the sample receiving regions 103a at a time (see col. 2, line 28 – col. 7, line 63; figure 6).

Yoshida does not specifically teach the incorporation of a transport mechanism that is configured to move one or more processing components proximal to or within each of two or more sample receiving regions at substantially the same time, wherein the sample processing components are configured to be inserted into the sample vessels when the sample vessels are present in the rotor.

Jovanovich does teach an automated centrifuge system comprising: a microplate bucket (43); centrifuge (42); and a transport mechanism (e.g., automated robot 102 comprising transfer head 104 containing capillary cassette 15) that is configured to move one or more processing

Art Unit: 1743

components (capillary tubes 12) proximal to or within each of two or more sample vessels (wells 36a of multiwell plate 36) at substantially the same time, wherein the sample processing components are configured to be inserted into the sample vessels when the sample vessels are present in the rotor (41) (see figures 1, 5A and 5B; col. 9, line 56 – col. 11, line 17).

As shown by Jovanovich, a person of ordinary skill in the art would accordingly have had a reasonable expectation for success in using a robotic transport mechanism for moving one or more processing components, i.e., sample fluid transfer tubes, proximal to or within two or more sample vessels, e.g., wells of a multi-well plate, at the same time and when the sample vessels are present within the rotor. The Courts have held that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02). In addition, the Courts have held that the mere duplication of parts, without any new or unexpected results, is within the ambit of one of ordinary skill in the art. See *In re Harza*, 124 USPQ 378 (CCPA 1960) (see MPEP § 2144.04). Furthermore, the applicant is advised that the United States Supreme Court recently clarified that a claim can be proved obvious merely by showing that the combination of known elements was obvious to try. In this regard, the U.S. Supreme Court explained that, “[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill in the art has a good reason to pursue the known options within his or her technical grasp.” An obviousness determination is not the result of a rigid formula disassociated from the consideration of the facts of the case. Indeed, the common sense of those skilled in the art demonstrates why some combinations would have been obvious where others would not. (“The

Art Unit: 1743

combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.”). See *KSR Int’l v. Teleflex Inc.*, 127 Sup. Ct. 1727, 1742, 82 USPQ2d 1385, 1397 (2007). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate the transport mechanism as claimed with the disclosed centrifuge device to facilitate effective sample processing.

Response to Arguments

Applicant's arguments with respect to the present claims have been considered, but are moot in view of the new ground(s) of rejection.

Conclusion

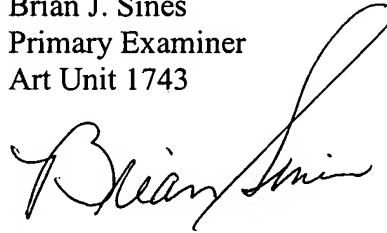
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines, Ph.D., whose telephone number is (571) 272-1263. The examiner can normally be reached on Monday - Friday (11 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1743

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Brian J. Sines
Primary Examiner
Art Unit 1743

A handwritten signature in black ink, appearing to read "Brian J. Sines", written in a cursive style.